Redefining ICD Indication

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Presenter Disclosure Information

Helmut U. Klein

Lecture honoraria (LH,)
Research grants (RG)
Consulting (C)

Boston Scientific, Inc. (RG,LH)
ZOLL-Lifecor Corp. (RG, C, LH)

The problem of ICD Therapy

J.A. Camm (EUROPACE 2013):

- “it’s time to revisit the therapy of sudden cardiac death”.
  For every 100 pts. implanted with an ICD, only 5-7 pts. experience a life-saving shock. The rest are exposed to the risks but get no benefit”

2013/2014

HRS/ACC/AHA Expert Consensus Statement on the Use of Implantable Cardioverter-Defibrillator Therapy in Patients Who Are Not Included or Not Well Represented in Clinical Trials

2014

APPROPRIATE USE CRITERIA

ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy

A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance

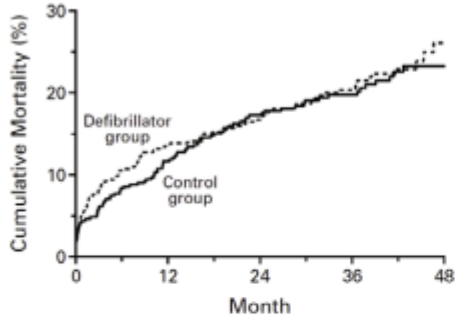
2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

The Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA).

Studies that formed guidelines

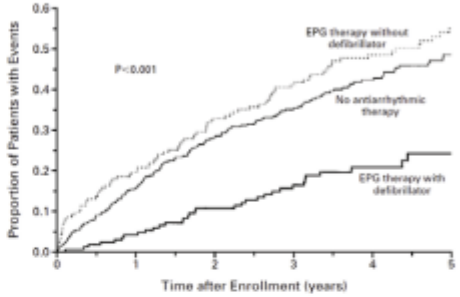
CAD: Cardiomyopathy

CABG-Patch

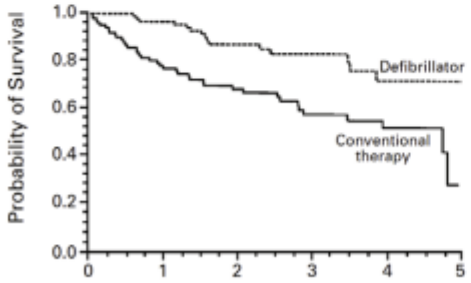


Defibrillator group	446	384	313	213	61
Control group	454	399	308	199	57

MUSTT

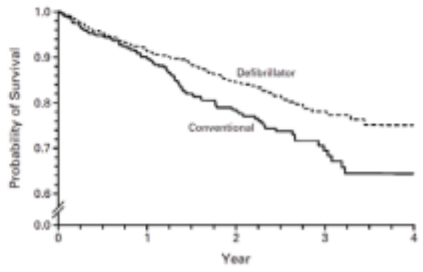


MADIT



No. of Patients						
Defibrillator	95	80	53	31	17	3
Conventional therapy	101	67	48	29	17	0

MADIT-II



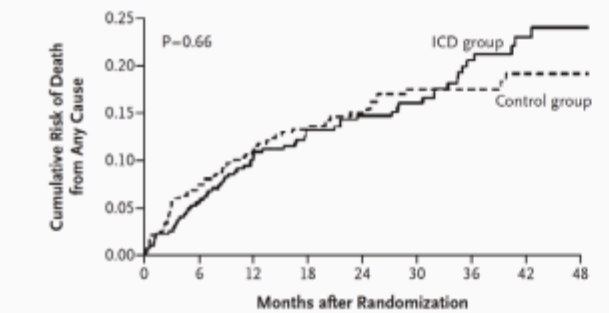
No. at Risk					
Defibrillator	742	503 (0.91)	274 (0.84)	110 (0.78)	9
Conventional	490	329 (0.90)	170 (0.78)	65 (0.68)	3

HRS/ACC/AHA Expert consensus statement;
Heart Rhythm 2014
doi.org/10.1016/j.hrthm.2014.03.041

Studies that formed guidelines

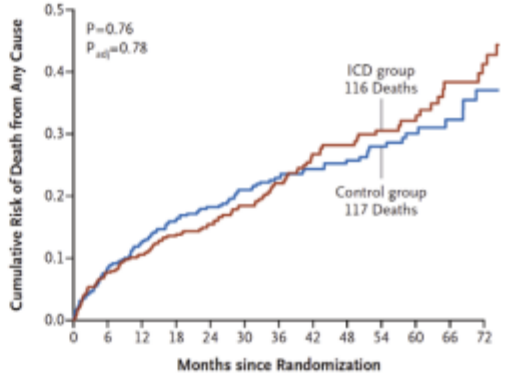
CAD: Acute MI

DINAMIT



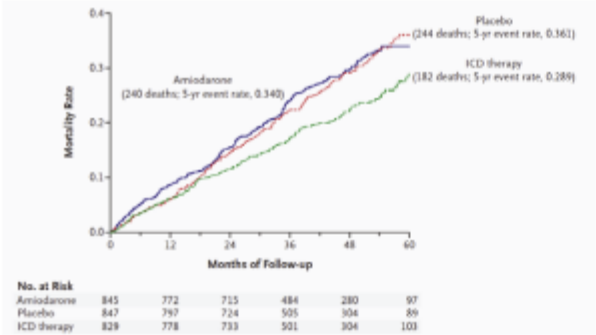
No. at Risk								
ICD group	315	299	258	211	172	123	82	25
Control group	318	305	272	217	172	124	79	31

IRIS



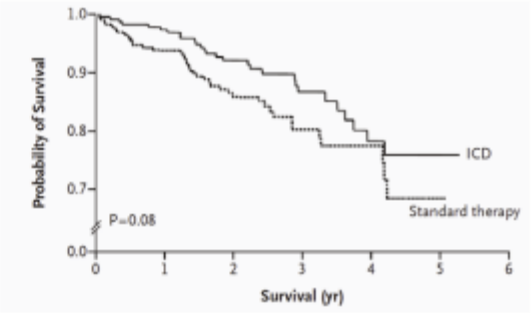
No. at Risk														
ICD group	445	390	366	338	303	253	207	163	137	106	78	48	40
Control group	453	410	380	336	307	267	230	187	151	118	79	49	36

Heart Failure
SCD-HeFT



No. at Risk						
Amiodarone	845	772	715	484	280	97
Placebo	847	797	724	505	304	89
ICD therapy	829	778	733	501	304	103

Nonischemic CM
DEFINITE



HRS/ACC/AHA Expert consensus statement; Heart Rhythm 2014 doi.org/10.1016/j.hrthm.2014.03.041

Current ICD Therapy

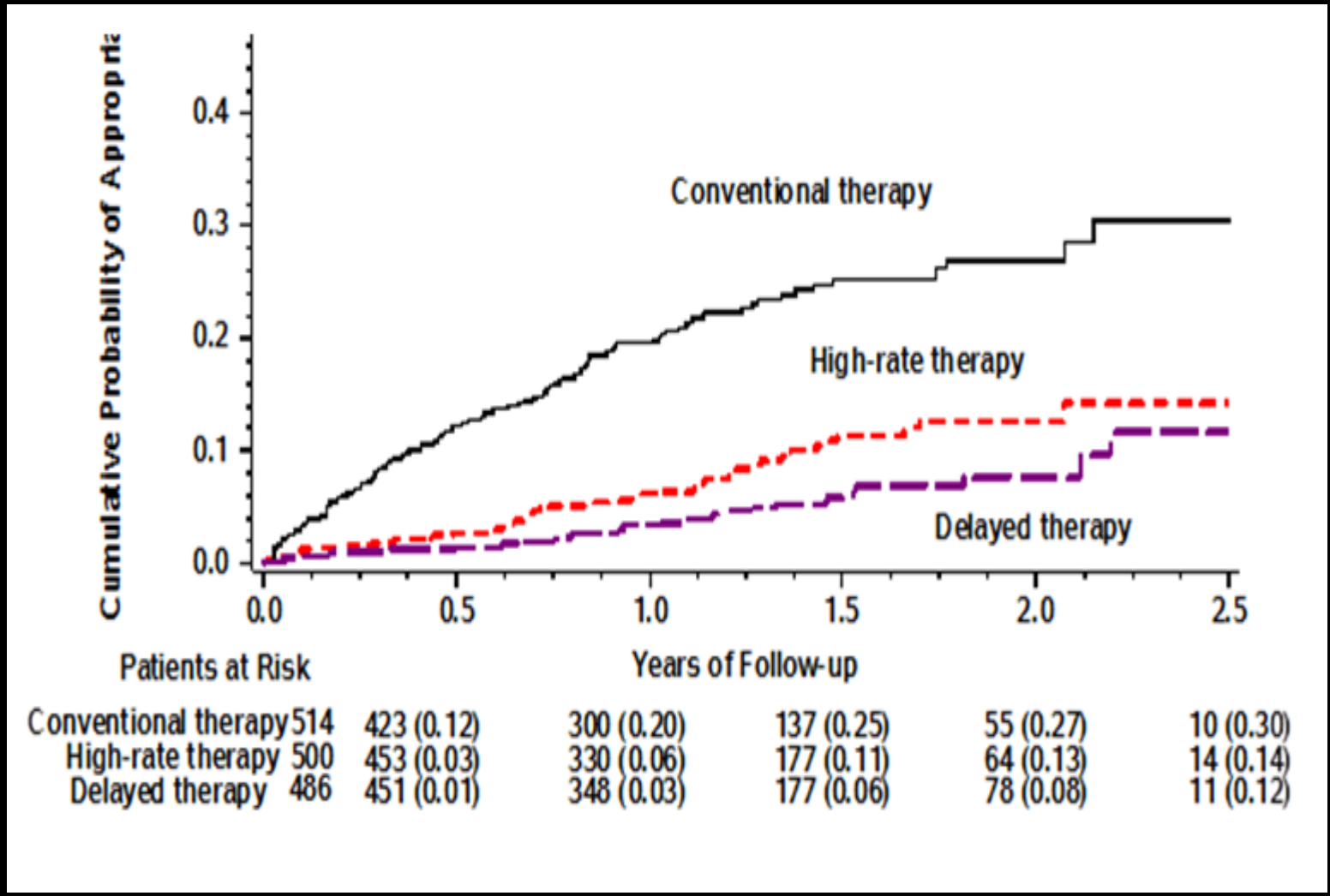
- Guidelines are based mostly on LVEF.
  However, LVEF is not a fixed parameter
- VT/VF events occur mostly with higher LVEF values
  (only 8% -10% VT/VF events/year with LVEF<35%)
- 5%-6% ICD complications / year
- 3%-6% implantation complications (recently 9.6%)
- 15%-19% complications with upgrading procedures
- 3%-5% ICD infection
  (more than twice as high after ICD replacement)
- 10%-15% inappropriate shocks
- 30% unnecessary shocks (MADIT-RIT)
- Device/ lead failure may always occur

What happened in recent years?

- The “clinical picture” of SCD has changed (circumstances, type of SCD, incidence, outcome)
- Less “Shockable rhythms”- more Asystole and Pulseless Electrical Activity (PEA)
- Less Ischemia- but more Heart failure
- Improved diagnostics (MRI, Genetic Testing)
- Programming went in the wrong direction

MADIT-RIT

Appropriate ICD Therapy



A.J .Moss et al. N Engl J Med, 2012; 367: 2275-83

The problem of self-terminating VT

Registration from a **W**earable **C**ardioverter **D**efibrillator (WCD)

Improved ICD programming

MADIT-RIT:

- Higher “Cut-off” VT rate (>200bpm)
- Delayed ICD therapy intervention (≥60sec)

ADVANCE III:

- Prolonged detection intervals (30/40 instead 18/24)

PREPARE:

- ATP for faster VT (>210bpm)

PAINFREE-SST:

- Improved detection algorithm (wavelet morphology, T-wave-discrimination, assessment of lead integrity/ noise, improved nsVT- Termination recognition)

Intrinsic RV:

- Avoiding unnecessary RV Pacing

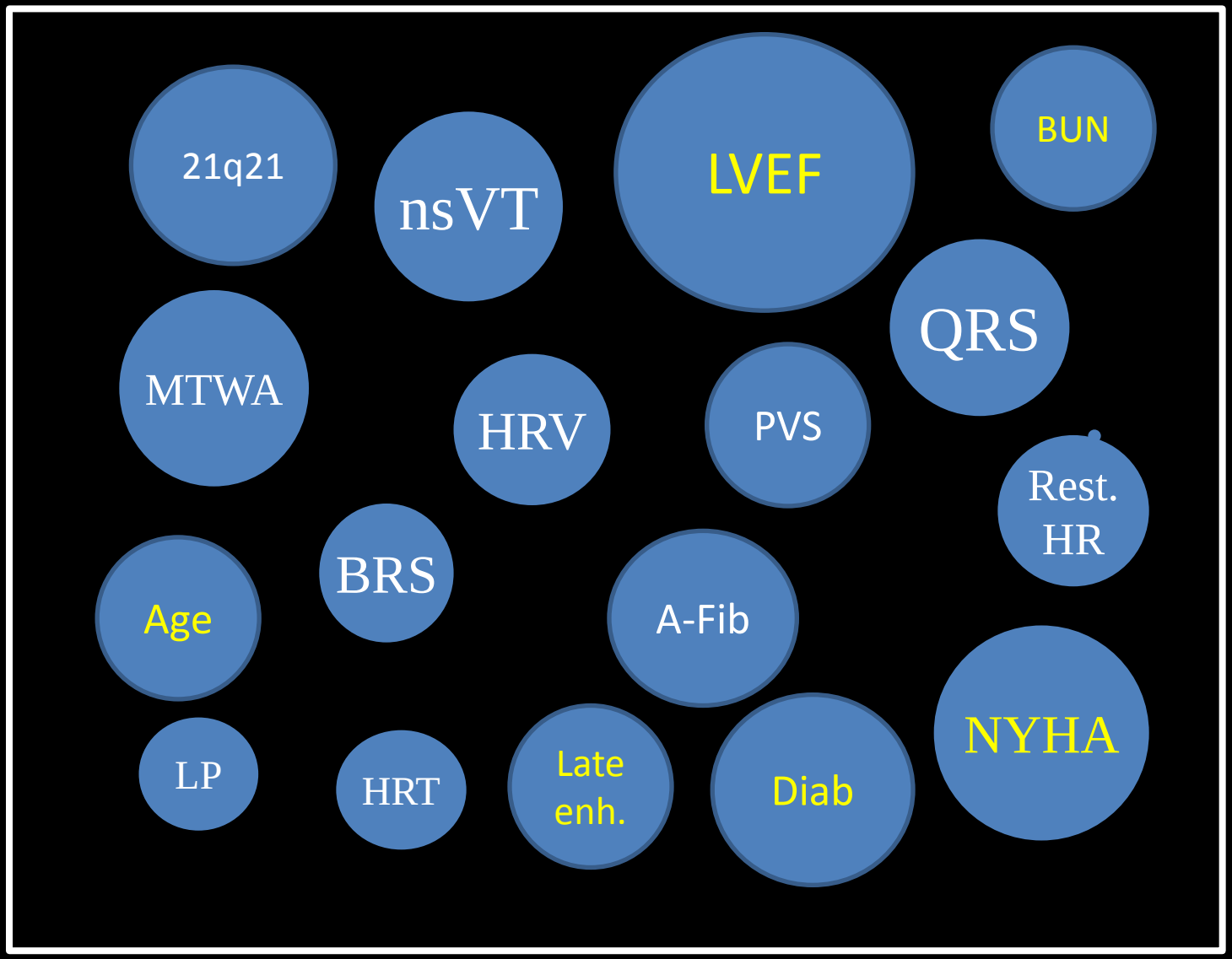
What did we learn in recent years?

- Better Programming (“less is more”)
- Need for a dual chamber ICD questioned
- No significant benefit of dual coil leads
- Unnecessary RV pacing is harmful
- Battery longevity has not significantly improved
- Technical problems are troublesome and expensive
- Is “Tele-monitoring” the solution and worth the money?

The problem of risk stratification

- Clinical practice almost exclusively uses LV-EF
- Although LV-EF yields a low positive predictive accuracy, guidelines are mostly based on LV-EF
- Other risk parameters (HRV, BRS, MTWA, late enhancement, biomarkers) may have even better positive predictive values- but they are rarely applied

The Riskfactor Pool



Who benefits most from ICD ?

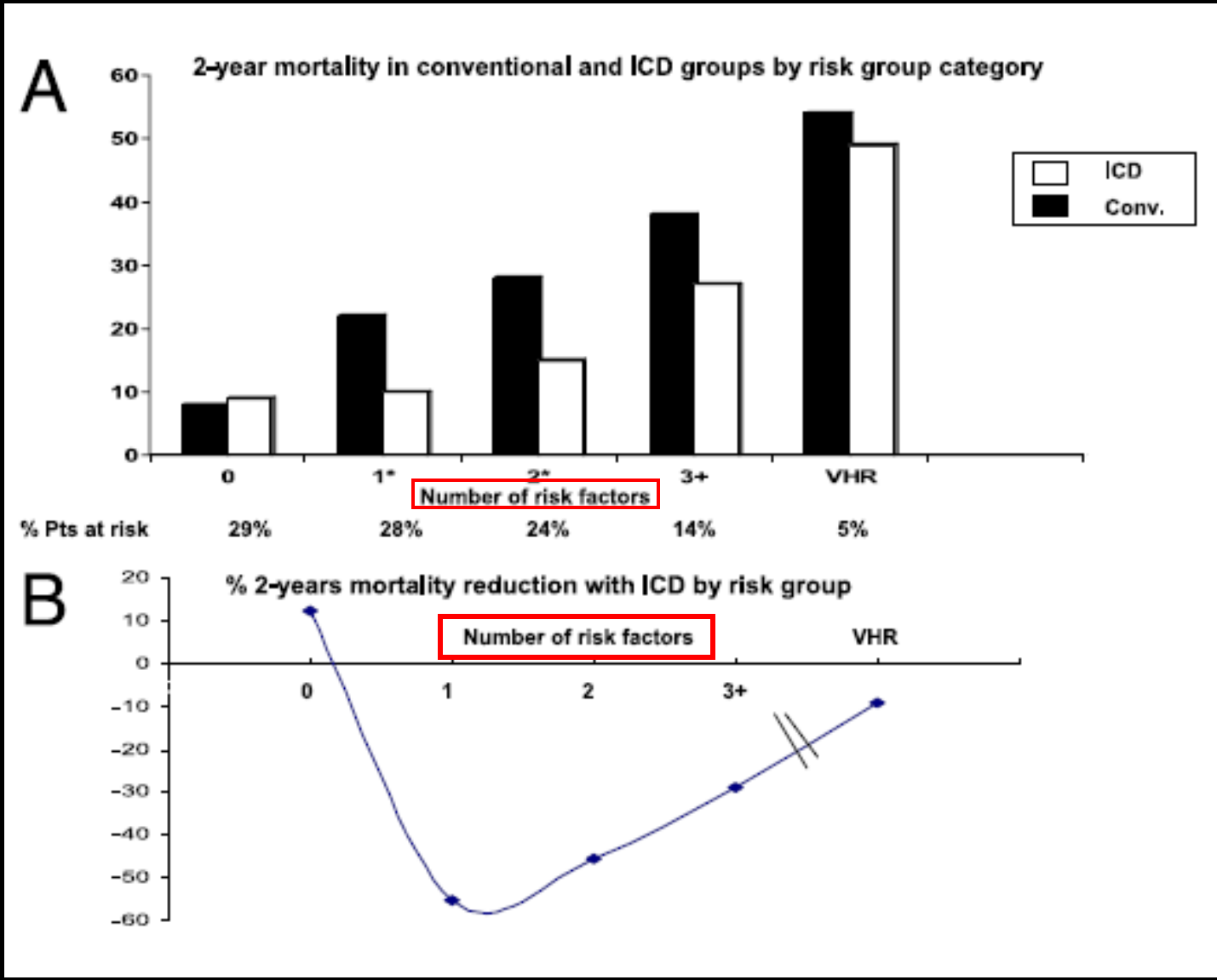
Clinical Risk Factors and Outcome (MADIT II)

Risk Factors:

- NYHA> II
- Age≥70a
- BUN>26mg/dl
- QRS>120ms
- A-Fib.

Very high R.F.:

- BUN ≥50 mg/dl
- Creat. ≥2.5 mg/dl



Goldenberg I, et al. JACC 2008; 51: 288

Guidelines

What do we have ?

- Classes I - II a - II b - III
- Levels of evidence (A,B,C)
- Indications may be:
  - indicated – not indicated
- Recommendations tell you:
  - is recommended - can be useful -
  - can be considered- is not recommended
- Indications are:
  - “appropriate (7-9)”
  - “may be appropriate (4-6)”
  - “rarely appropriate (1-3)”

Guidelines

What do we need ?

- Definitions and Time-zones for AMI
- Definitions for Heart Failure,
  - Diagnostic time-zones for heart failure
  - Treatment time-zones for heart failure
- Definitions for ischemic and non-ischemic cardiomyopathy
- Definitions of co-morbidity

Patient risk too high?

- What is a "reasonable expectation of a meaningful survival > 1 year"?
- The ICD is a device to treat VT/VF-nothing more and nothing less; overall survival may depend on completely different problems
- Impact of severe co-morbidities (diabetes, renal dysfunction, cancer, hemodialysis, cerebral function, etc.)
- NYHA class IV
- Quality of life; psychiatric situation??

AMI ≤ 40 days

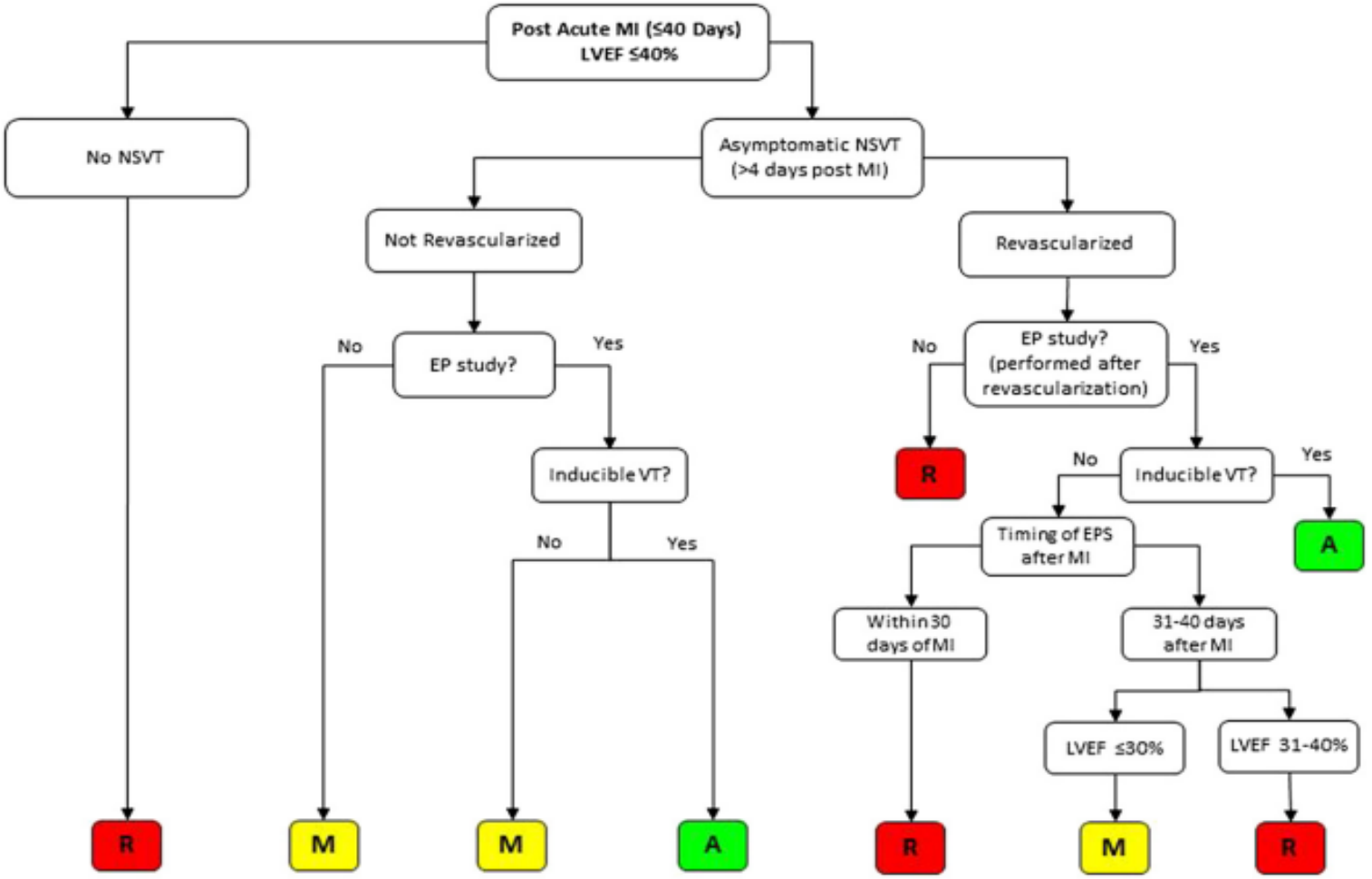


Figure 9 Primary Prevention: Coronary Artery Disease, Post-Acute MI (≤40 Days), LVEF ≤40%
A = Appropriate; EP = electrophysiological; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NSVT = nonsustained ventricular tachycardia; R = Rarely Appropriate; VF = ventricular fibrillation; VT = ventricular tachycardia.

Appropriate use criteria
A.M. Russo et al. Heart Rhythm 2013; 10:11-58

Post-MI > 40 days

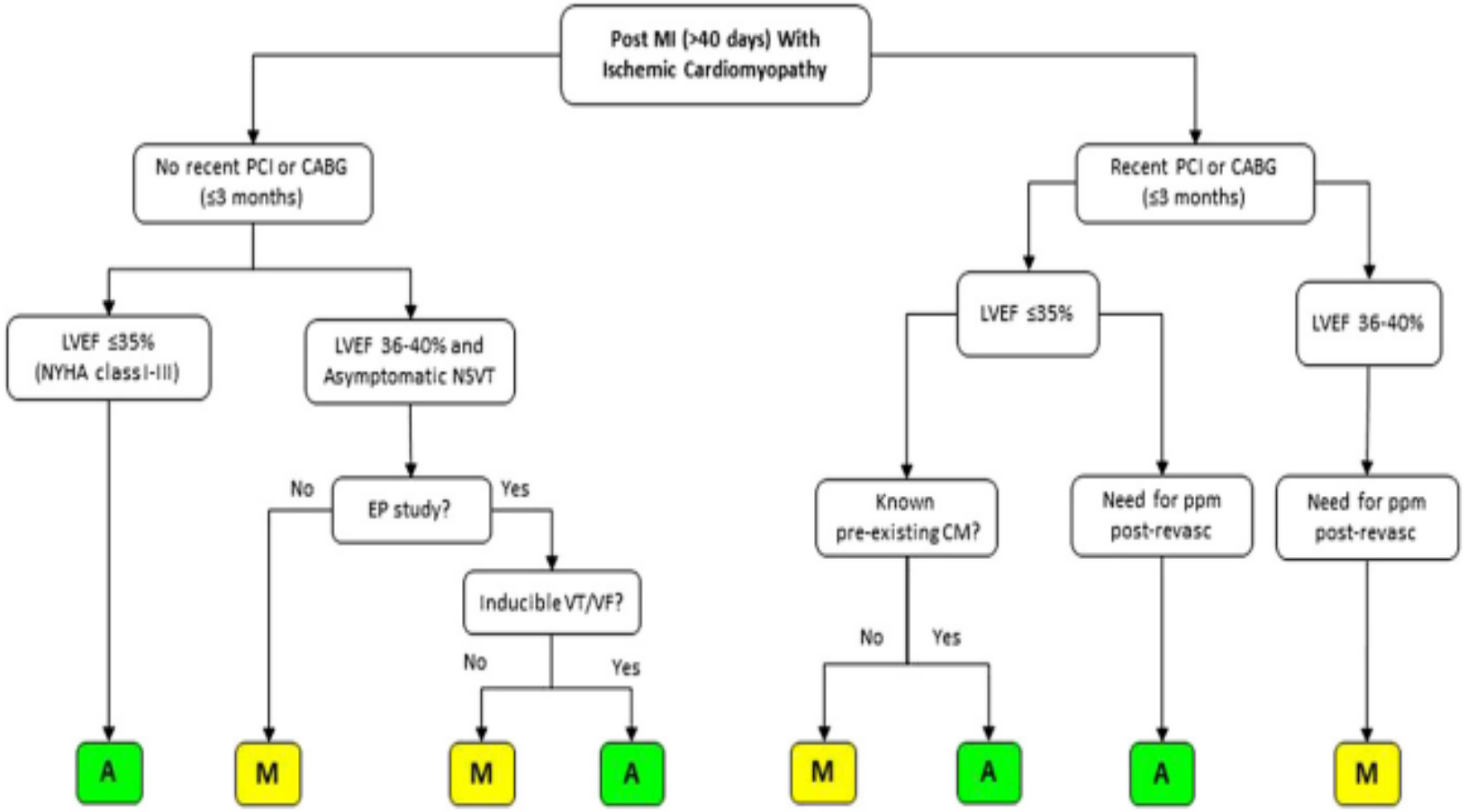


Figure 10 Primary Prevention: Coronary Artery Disease, Prior MI (>40 Days) With Ischemic Cardiomyopathy

A = Appropriate; CABG = coronary artery bypass graft; CM = cardiomyopathy; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NSVT = nonsustained ventricular tachycardia; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; ppm = permanent pacemaker; VF = ventricular fibrillation; VT = ventricular tachycardia.

Appropriate use criteria
A.M. Russo et al. Heart Rhythm 2013; 10:11-58

Non-ischemic cardiomyopathy

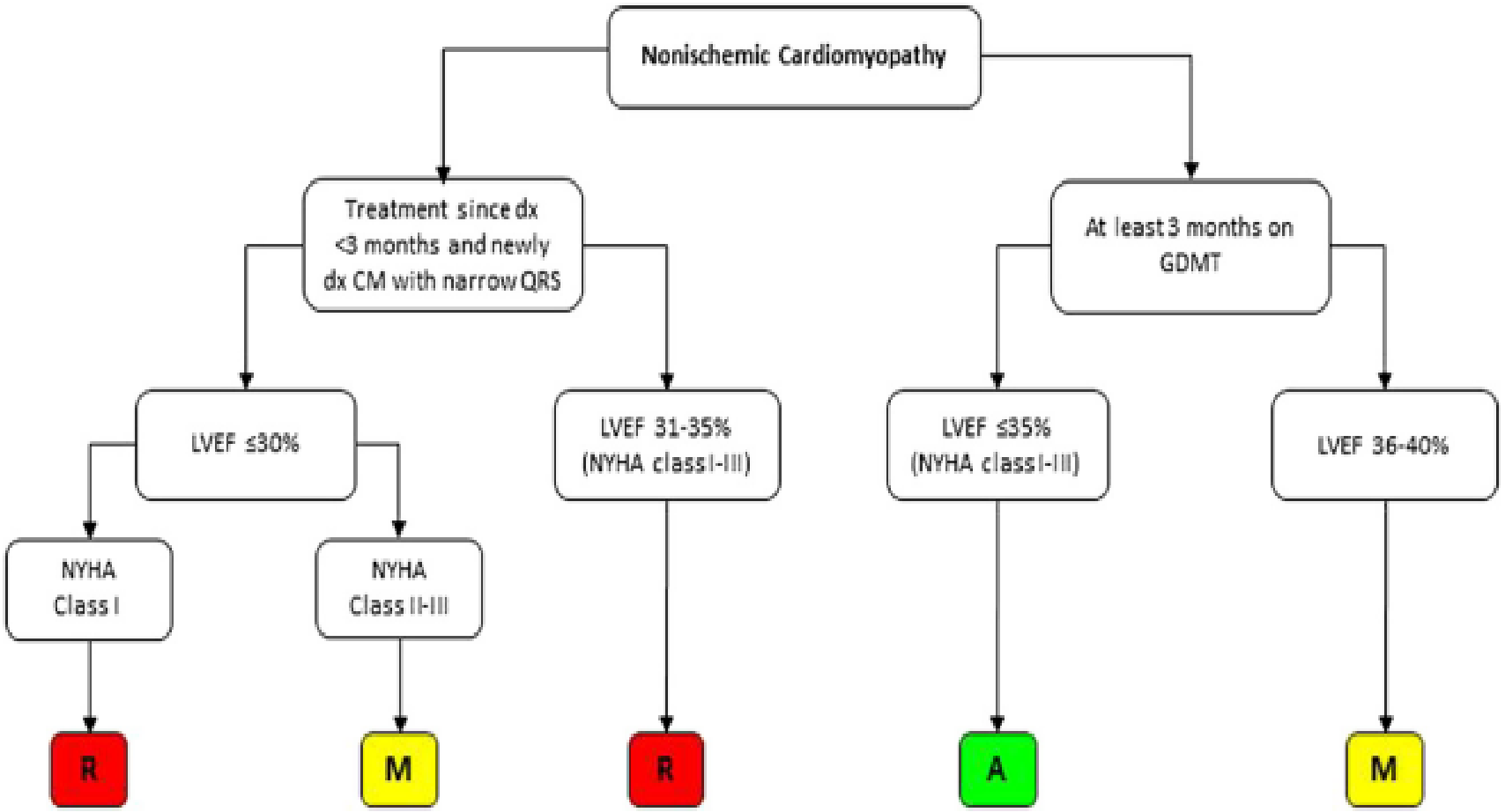


Figure 11 Primary Prevention: Nonischemic Cardiomyopathy

A = Appropriate; CM = cardiomyopathy; dx = diagnosis; GDMT = guideline-directed medical therapy; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate.

Appropriate use criteria

A.M. Russo et al. Heart Rhythm 2013; 10:11-58

Non-ischemic cardiomyopathy (Specific etiologies)

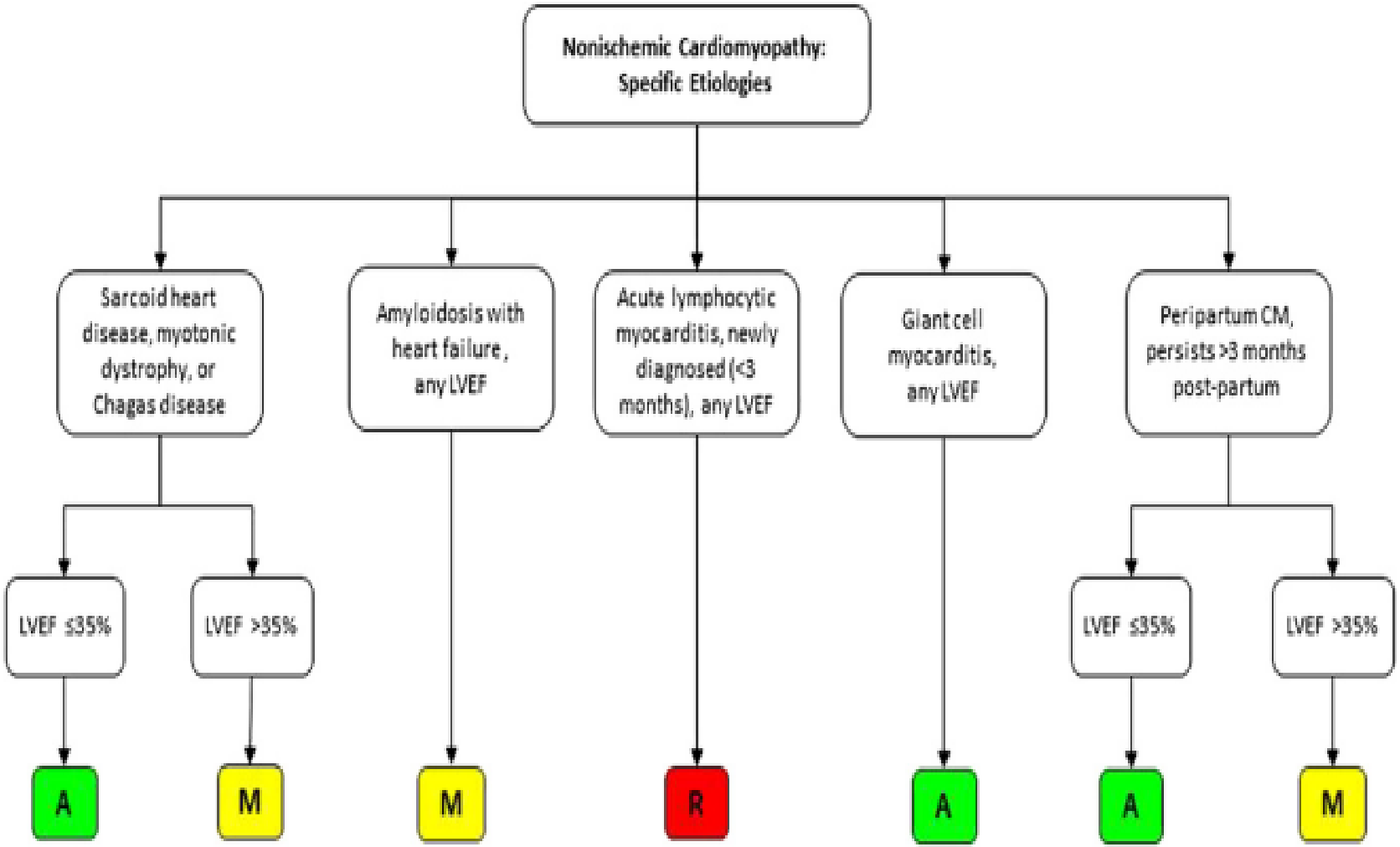


Figure 12 Primary Prevention: Nonischemic Cardiomyopathy, Specific Etiologies

A = Appropriate; CM = cardiomyopathy; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate.

Appropriate use criteria

A.M. Russo et al. Heart Rhythm 2013; 10:11-58

Unexplained Syncope

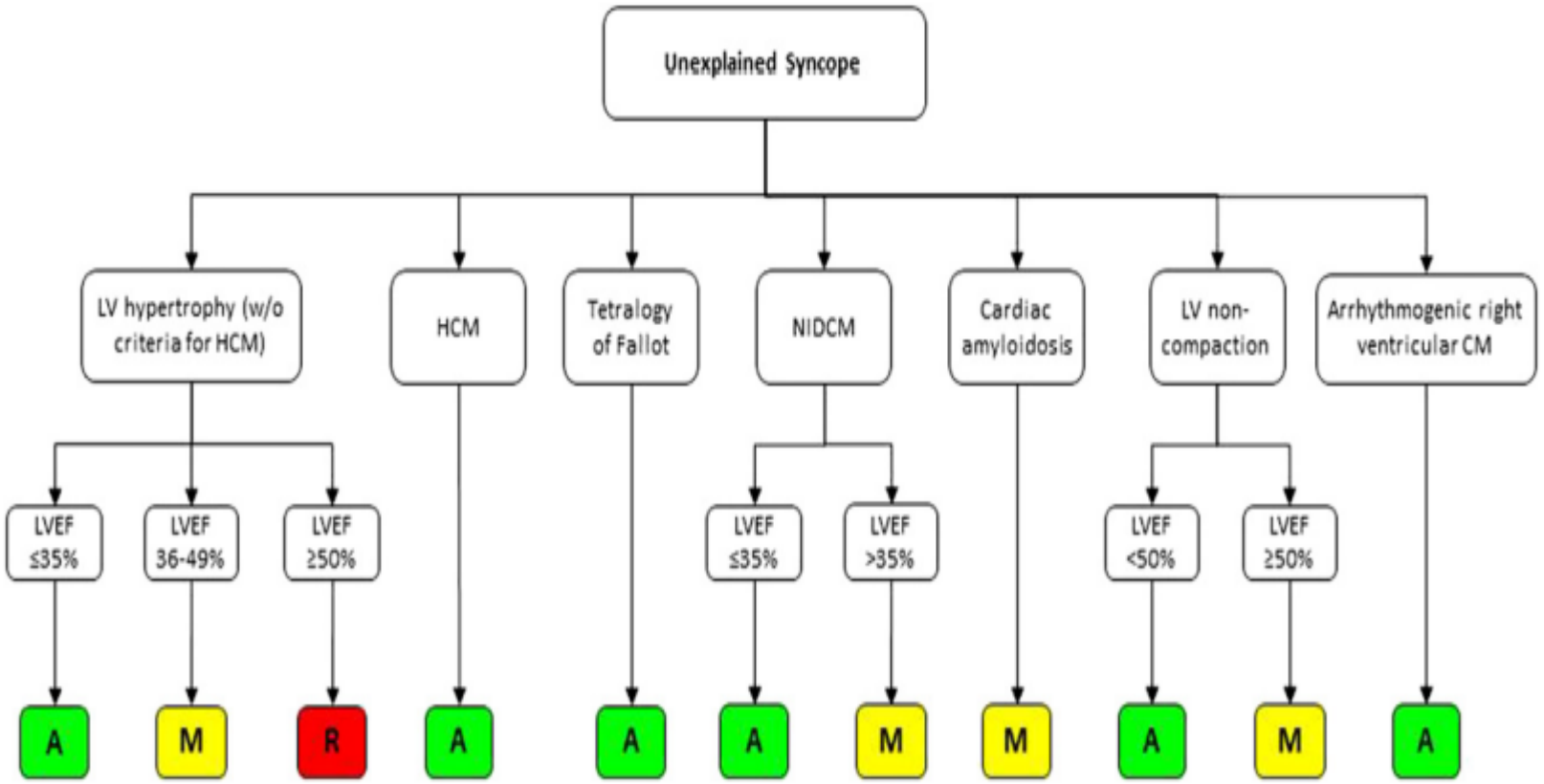


Figure 7 Secondary Prevention: Syncope in Patients with Nonischemic Structural Heart Disease

A = Appropriate; CM = cardiomyopathy; HCM = hypertrophic cardiomyopathy; LV = left ventricular; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NIDCM = nonischemic dilated cardiomyopathy; R = Rarely Appropriate.

Appropriate use criteria
A.M. Russo et al. Heart Rhythm 2013; 10:11-58

Inherited Arrhythmia Syndromes and Specific Genetic diseases

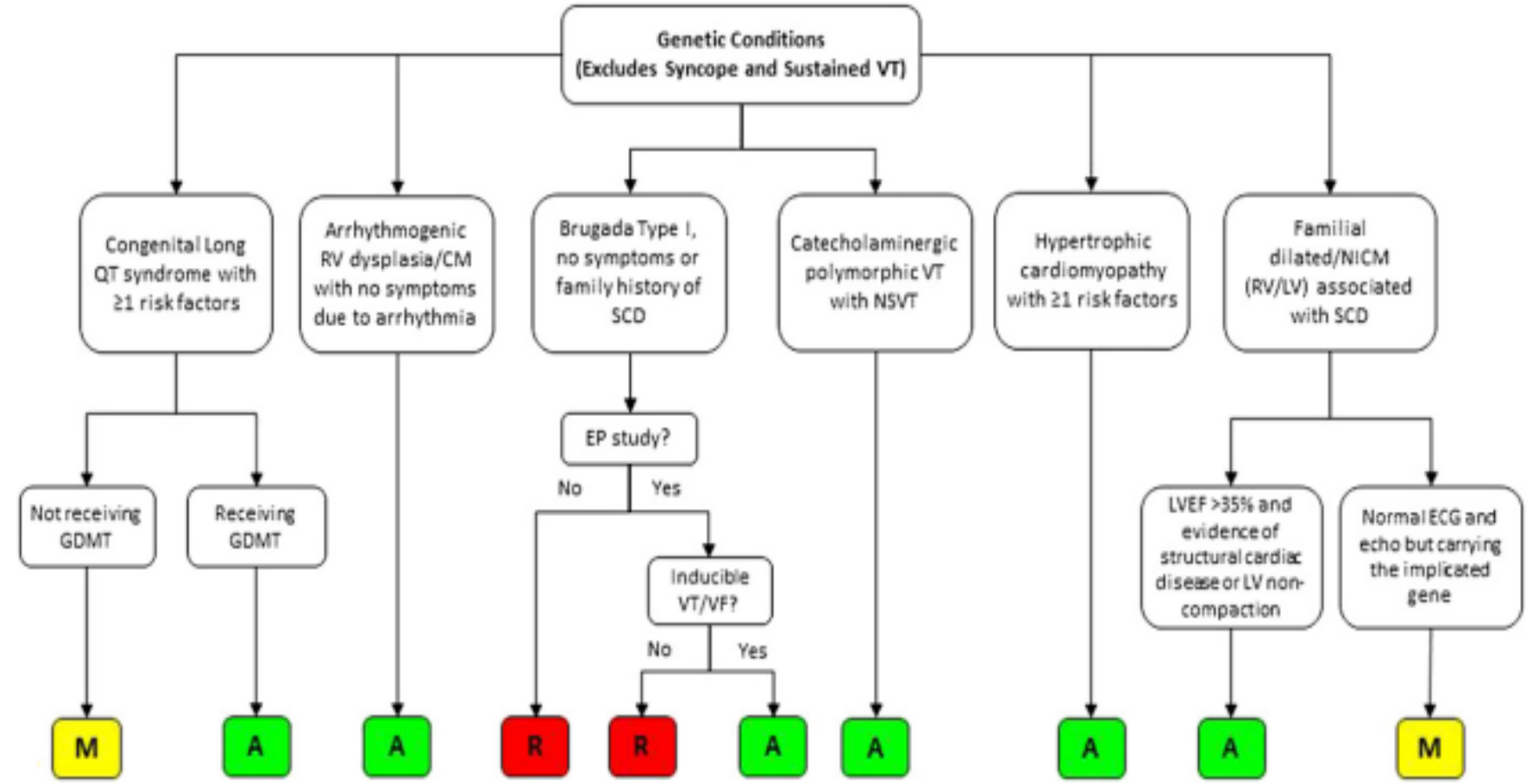


Figure 13 Primary Prevention: Genetic Conditions (Excludes Syncope and Sustained VT)

A = Appropriate; CM = cardiomyopathy; ECG = electrocardiogram; EPS = electrophysiological study; GDMT = guideline-directed medical therapy; LV = left ventricular; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NICM = nonischemic cardiomyopathy; NSVT = nonsustained ventricular tachycardia; R = Rarely Appropriate; RV = right ventricular; SCD = sudden cardiac death; VF = ventricular fibrillation; VT = ventricular tachycardia.

Appropriate use criteria
A.M. Russo et al. Heart Rhythm 2013; 10:11-58

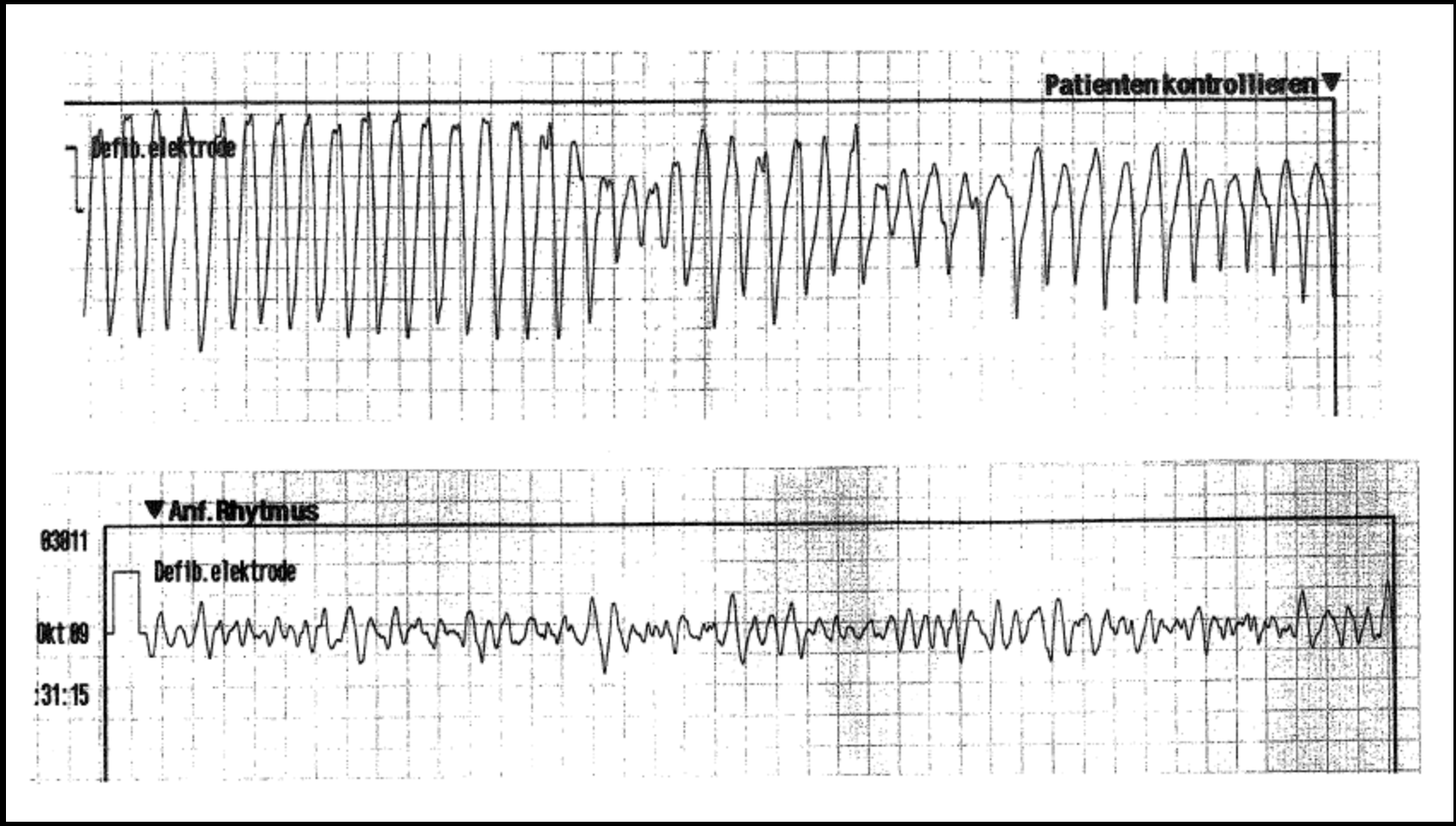
Are these flow charts really helpful- or are they confusing ?

for physicians ?

for patients ?

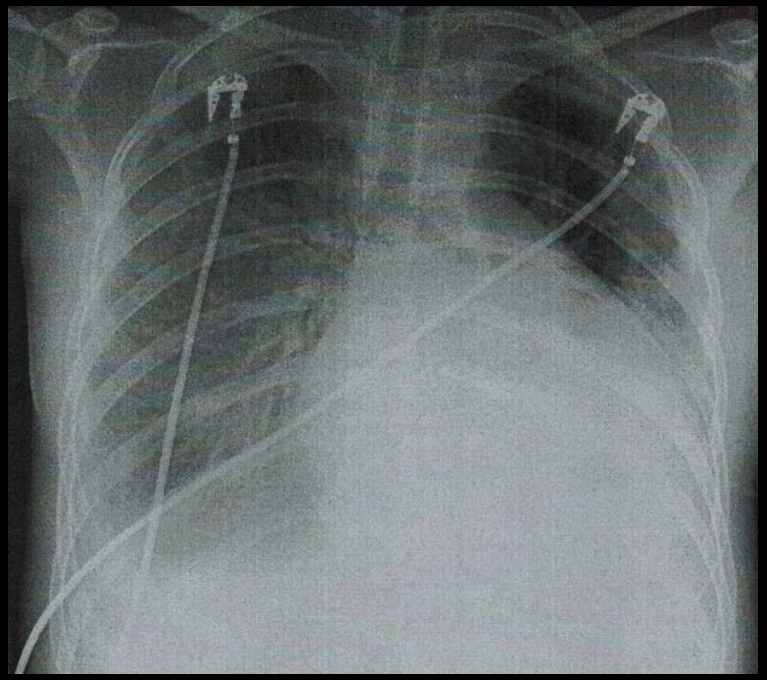
for our healthcare system?

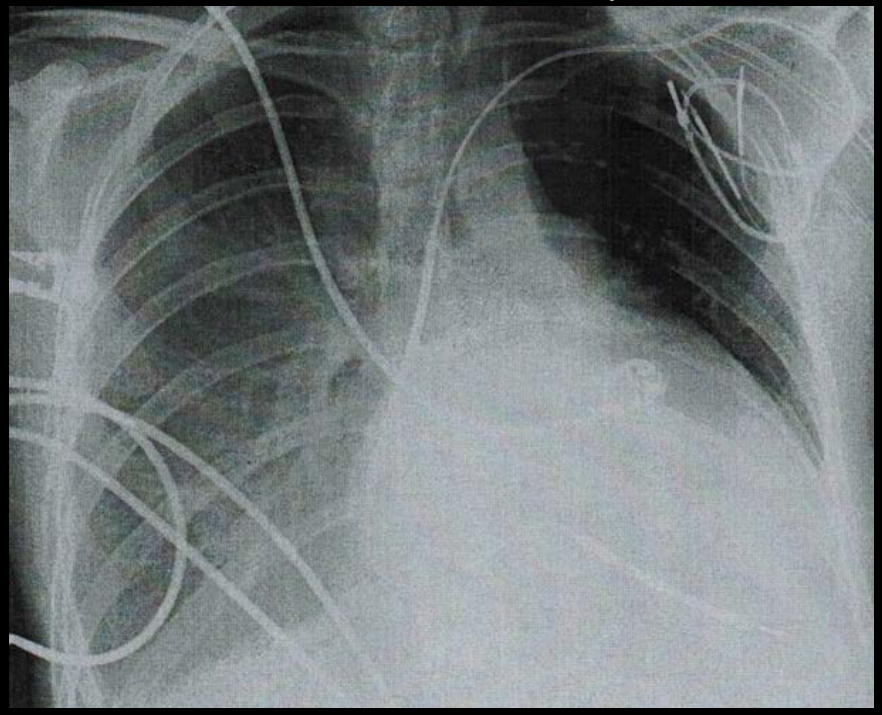
Rhythm strip from the Paramedics at the time of cardiac arrest

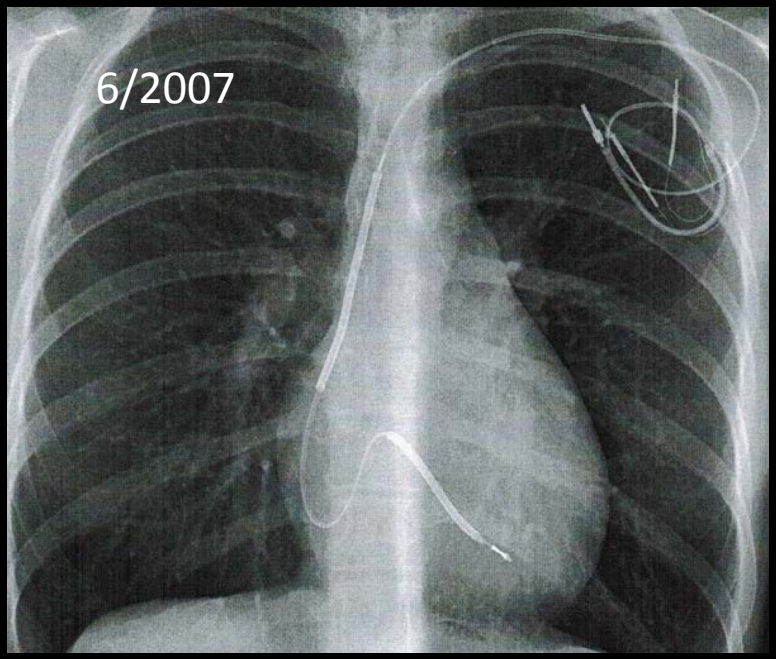


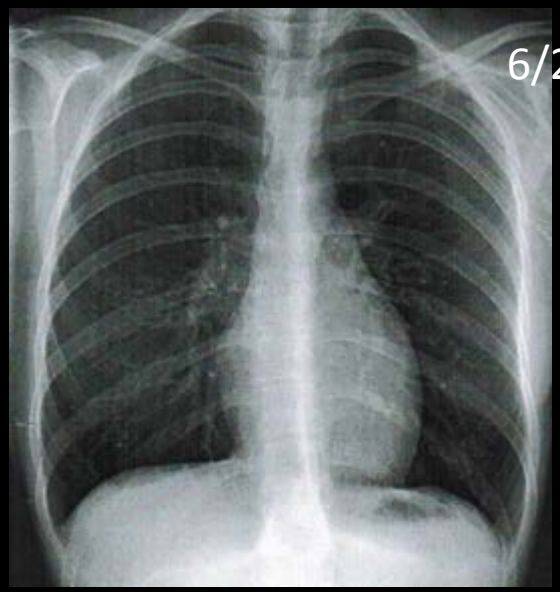
K.W. 54 years

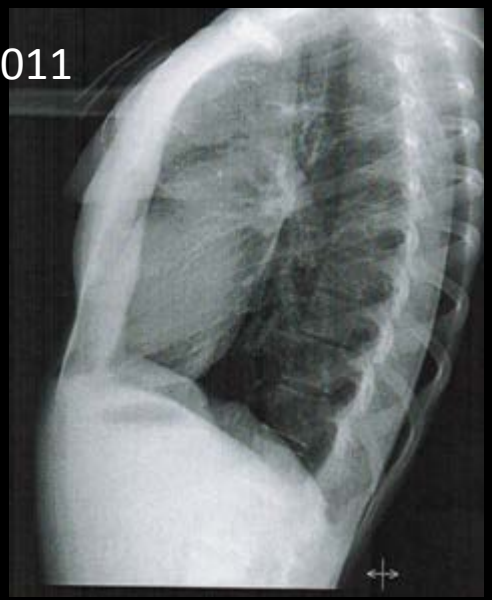
24 y old female











Courtesy Prof. J. Winter

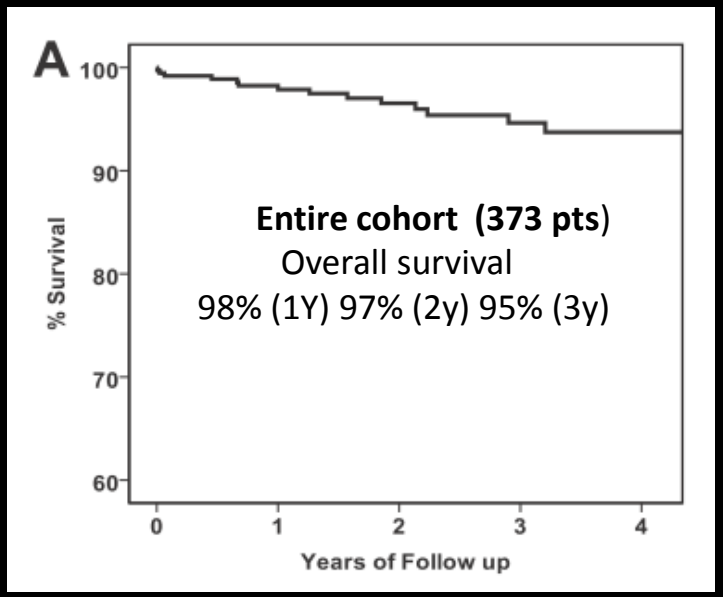
ICD and SCD in recent onset of Non-ischemic Cardiomyopathy (NICM)

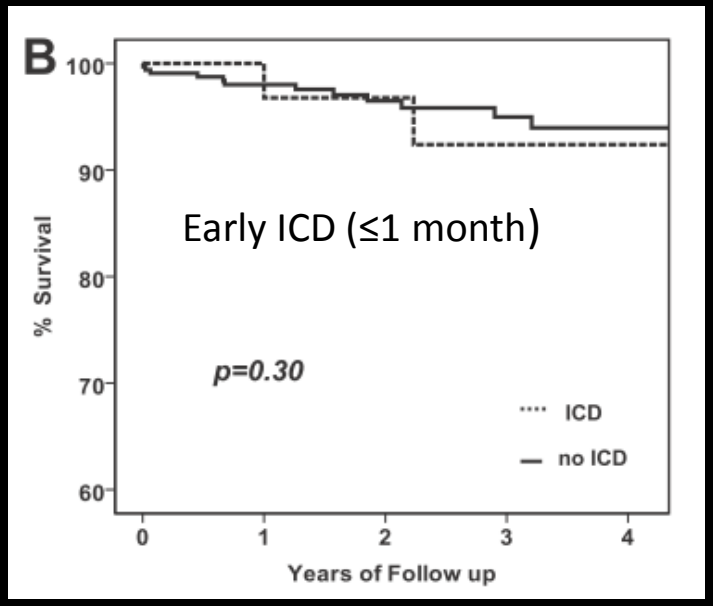
373 pts;
mean baseline LVEF: 24%
mean LVEF after 6 months: 42%

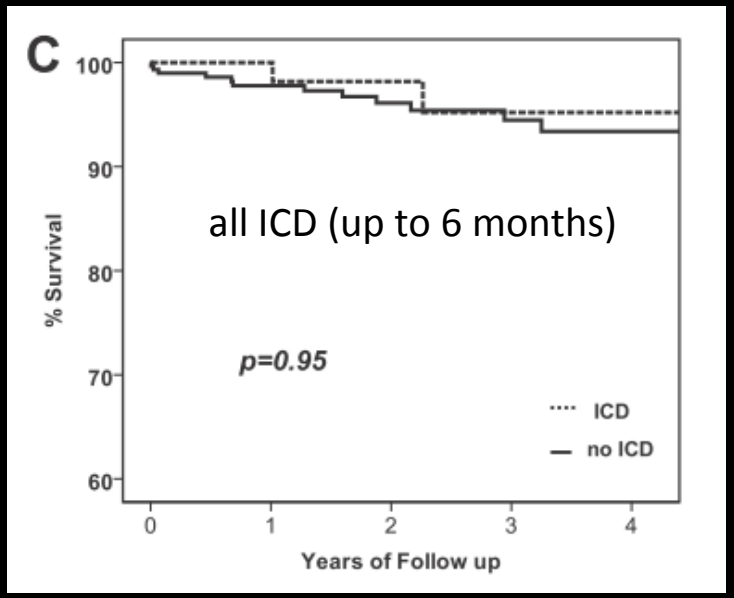
- 43 pts with early ICD (<1 month)
- 30 pts late ICD (1-6 months)

Overall mortality:

- 10 pts without ICD (3.8%)
- 5 pts with ICD (4.6%)







R. Sheppard et al. J Cardiac Fail 2012; 18: 675-81 (IMAC 2 Registry)

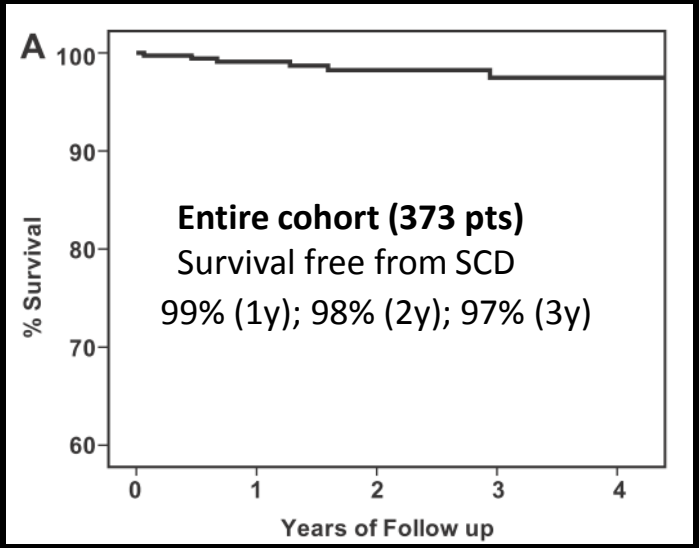
ICD and SCD in recent onset of NICM

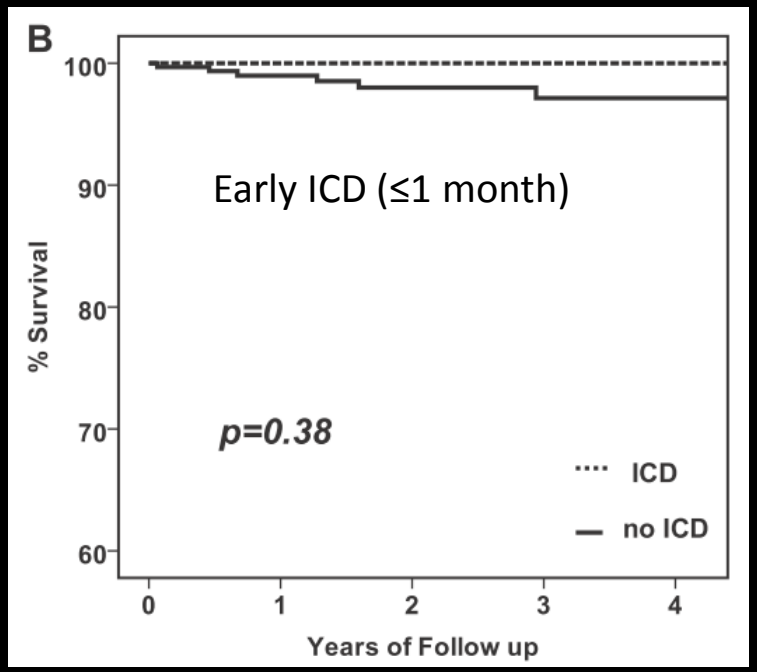
6 pts. with SCD:

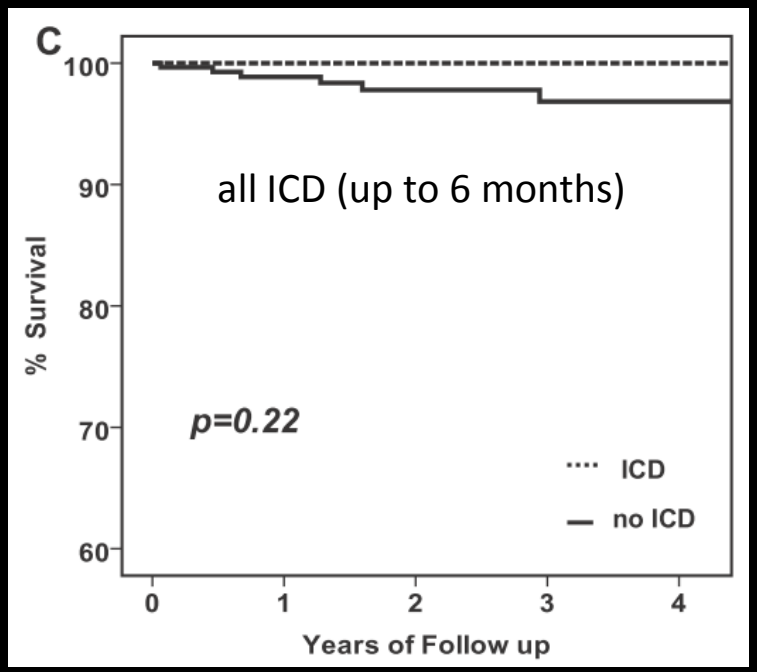
after mean of 420 days

5 pts. (1.9%) without ICD
1 pt. (0.9%) with ICD

8 pts. with VT





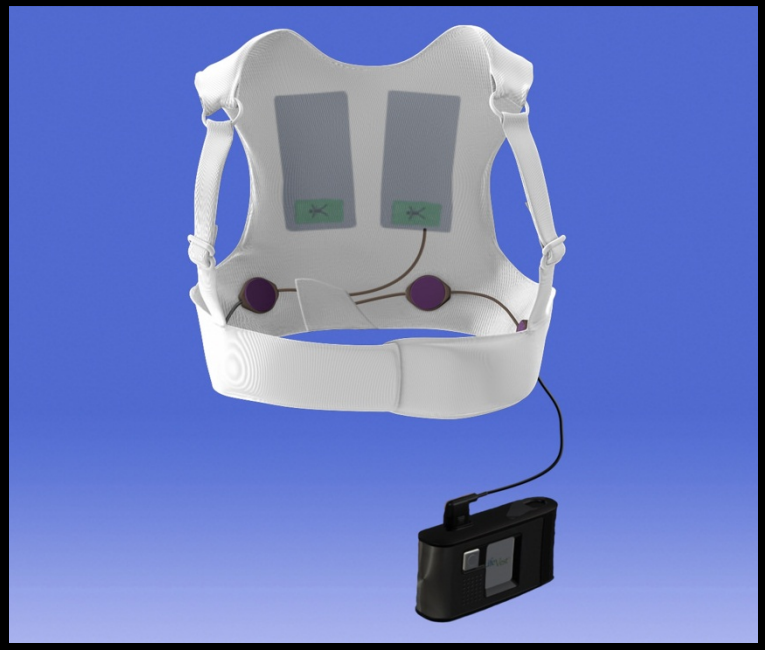


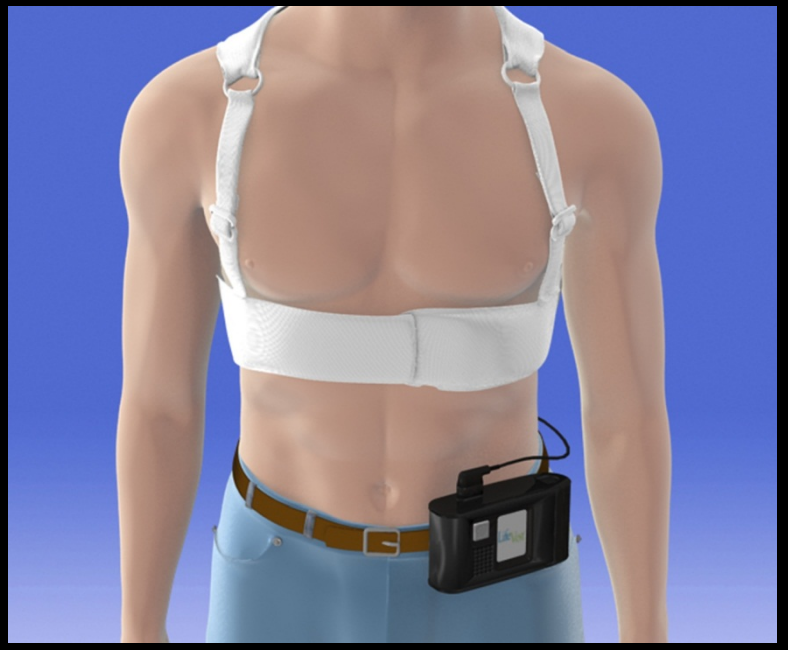
R. Sheppard et al. J Cardiac Fail 2012; 18: 675-81 (IMAC2 Registry)

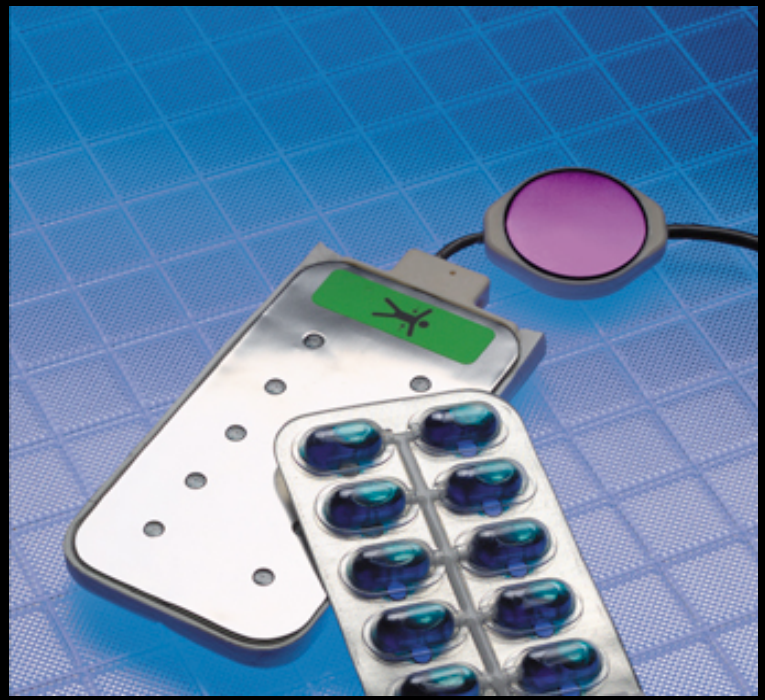
The concept of the WCD

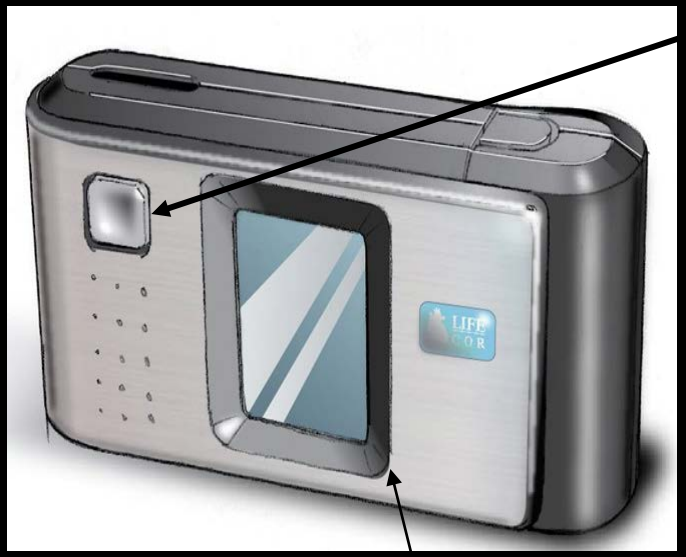
- The WCD is an approach to bridge an undetermined time period of risk stratification to either confirm - or disregard a permanent risk of SCD

- During wearing time of the LifeVest® the patient is protected by the defibrillator,
- meanwhile the care giving physician has time to monitor the clinical status, assess structural changes of the heart, analyze risk parameters and
- to monitor continuously the occurrence of dangerous arrhythmias.









RB

LCD

LifeVest 4000

Results From The Prospective Registry of Patients using the Wearable Defibrillator

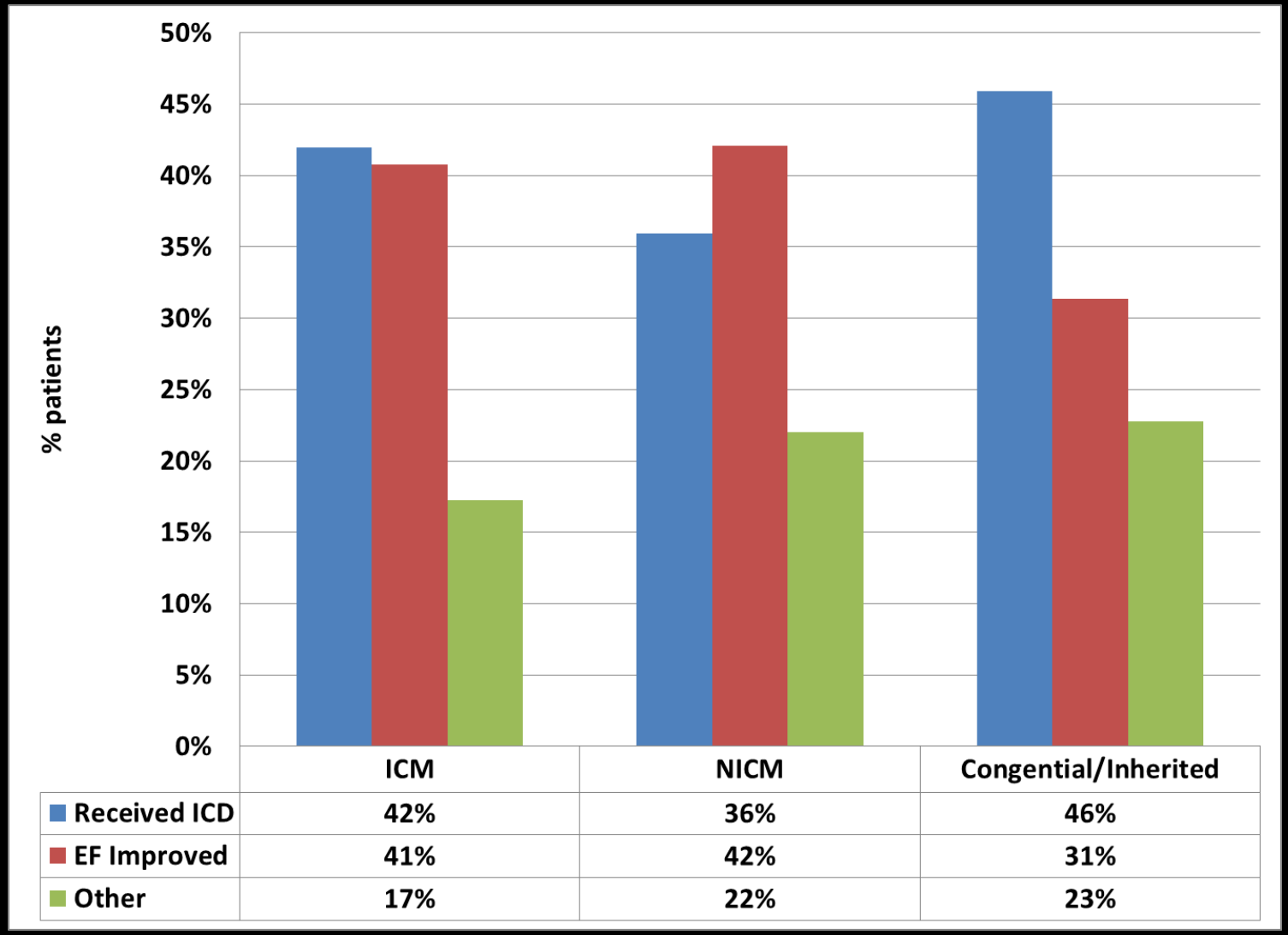
WEARIT-II Registry

Late Breaking Trials ESC Barcelona 2014

Valentina Kutyifa, Ilan Goldenberg, Wojciech Zareba,
Helmut Klein, Chingping Wan, Bonnie MacKecknie,
Mark L. Andrews, Steve Szymkiewicz, Arthur J. Moss,

Cardiology Division, Department of Medicine
University of Rochester Medical Center,
Rochester, N.Y, USA

ICD Implantation rate by disease etiology

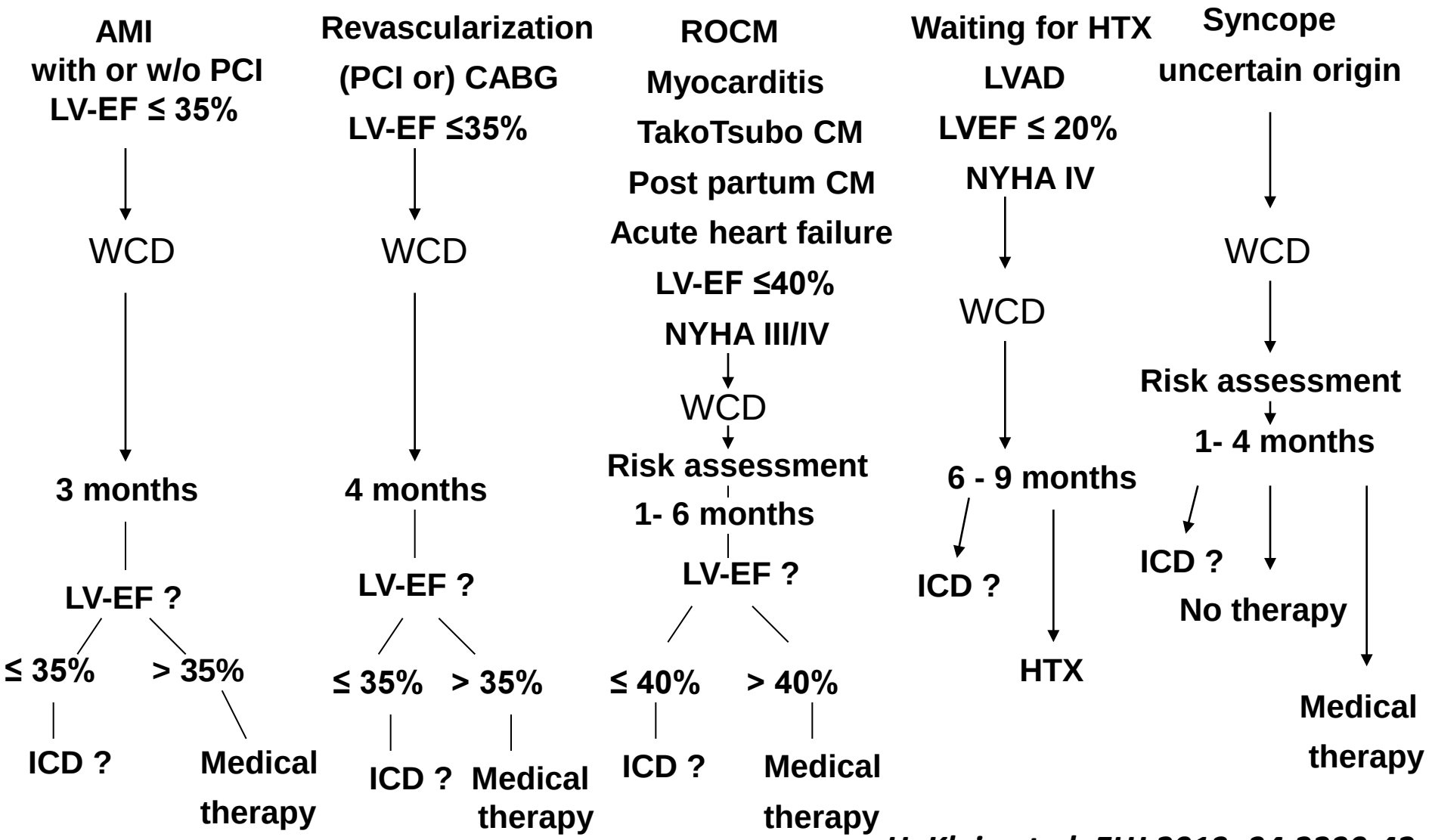


	ICM	NICM	Congential/Inherited
Received ICD	42%	36%	46%
EF Improved	41%	42%	31%
Other	17%	22%	23%

Late Breaking Trials ESC Barcelona 2014

Risk assessment for ICD Therapy

Use of the Wearable Cardioverter-Defibrillator (WCD)



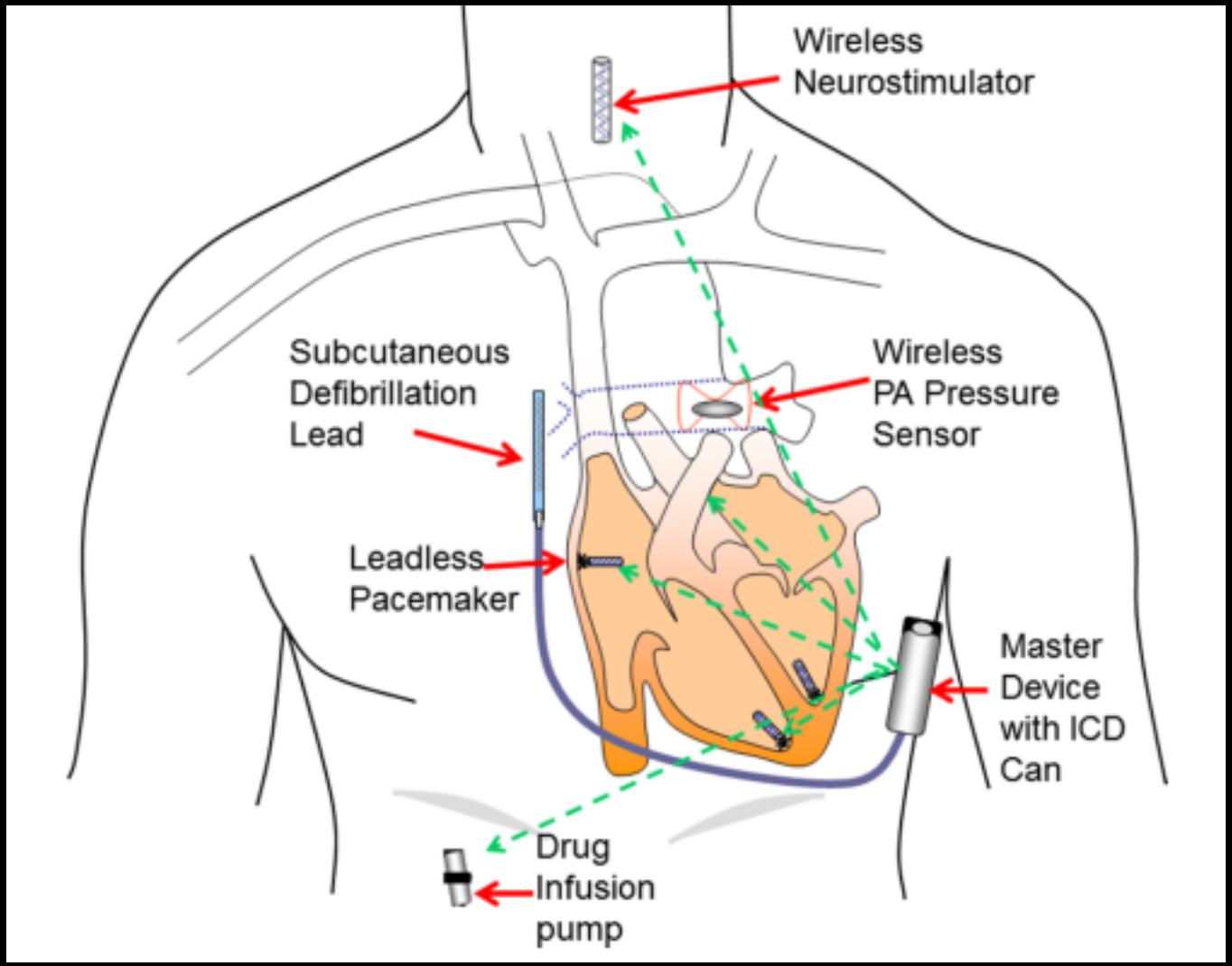
H. Klein et al. EHJ 2013; 34:2230-42

Conclusion

… we must continue to refine our understanding of who benefits from ICD implantation and how to optimally implement ICD therapy in patients who are at risk of life-threatening ventricular arrhythmias

HRS/ACC/AHA Expert Consensus Statement
F.M. Kusumoto et al.
Heart Rhythm 2014

The futuristic implanted device for cardiac rhythm management



C.-P. Lau et al. Circulation 2014; 129: 811-822